NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

APTALIS PHARMA US, INC., et al., : CIVIL ACTION NO. 15-8637 (MLC)

Plaintiffs, : **MEMORANDUM OPINION**

V.

PHARMACEUTICAL SOURCING PARTNERS, INC.,

Defendant.

THE PLAINTIFFS: (1) "market[] a mesalamine rectal suppository product known as Canasa", which "is approved for the treatment of active ulcerative proctitis"; and (2) allege that the defendant is engaging in infringement by seeking approval from the United States Food and Drug Administration ("FDA") in an Abbreviated New Drug Application ("ANDA") to sell a generic version. (Dkt. 19-1 at 6; dkt. 1 at 4.) The defendant asserts counterclaims for, inter alia: (1) unfair competition under state law

("Unfair Competition Counterclaim"); and (2) tortious interference ("Tortious

Interference Counterclaim"). (Dkt. 7 at 17–19, 22–23.)

THE PLAINTIFFS move either: (1) to dismiss the Unfair Competition

Counterclaim and Tortious Interference Counterclaim (collectively, "Counterclaims At

Issue") pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(6); or (2) to bifurcate

and stay discovery concerning the Counterclaims At Issue pending the resolution of the

plaintiffs' infringement claims. (See dkt. 19 through dkt. 19-3; dkt. 22.) The defendant opposes the motion in its entirety. (See dkt. 20 through dkt. 20-7.)

THE COURT presumes the familiarity of the parties with the factual context and procedural history of the action, and will resolve the motion without oral argument. See L.Civ.R. 78.1(b). For the following reasons, the motion insofar as it concerns: (1) dismissal of the Unfair Competition Counterclaim will be denied; (2) dismissal of the Tortious Interference Counterclaim will be denied; and (3) bifurcation and a stay will be denied without prejudice.

THE COURT will not restate the standard for resolving a motion made pursuant to Rule 12(b)(6) to dismiss a counterclaim. See New Skies Satellites v. Home2US

Commc'ns, 9 F.Supp.3d 459, 464–65 (D.N.J. 2014) (setting forth standard; citing

Ashcroft v. Iqbal, 556 U.S. 662 (2009), and Bell Atl. Corp. v. Twombly, 550 U.S. 544

(2007)); PPG Indus. v. Generon IGS, 760 F.Supp.2d 520, 524 (W.D. Penn. 2011) (setting forth standard; citing Iqbal); see also United States v. Jallali, 478 Fed.Appx. 578, 579

(11th Cir. 2012) (setting forth standard; citing Iqbal).

A COUNTERCLAIM alleging unfair competition may encompass allegations concerning interference with the potential marketing of a generic pharmaceutical product.

See Warner Lambert Co. v. Purepac Pharm. Co., No. 98-2749, 2000 WL 34213890, at *10–11 (D.N.J. Dec. 22, 2000) (relying on <u>Duffy v. Charles Schwab & Co.</u>, 97 F.Supp.2d 592, 601 (D.N.J. 2000), which addresses notion that unfair competition is a broad

category). The defendant has sufficiently pleaded the Unfair Competition Counterclaim by alleging that the plaintiffs: (1) asserted in filings with the United States Securities and Exchange Commission that they lacked patent protection in the United States for their Canasa products, which the defendant relied upon as it developed a generic; (2) sought to patent their Canasa product after it was introduced for sale; and (3) publicly stated that they were seeking patent protection for a formulation that differed from the formulation of the product at issue. (See dkt. 7 at 18–19; dkt. 20 at 7–9; see also dkt. 20-2 at 5 (plaintiffs' statement that "CANASA does not have any patent protection in the U.S."); id. at 7 (same).) Thus, the Court will deny the part of the motion seeking to dismiss the Unfair Competition Counterclaim.

THE DEFENDANT has also sufficiently pleaded the Tortious Interference

Counterclaim. First, the defendant — in alleging that it conducted research and filed an ANDA with the goal of selling a generic product, only to have the process now stayed — has properly pleaded that it had a "reasonable expectation of economic benefit or advantage". Lightning Lube v. Witco Corp., 4 F.3d 1153, 1167 (3d Cir. 1993). Second, the defendant — in pointing out (a) the plaintiffs' statements concerning the lack of patentability of their Canasa products, (b) the defendant's communications with the plaintiffs concerning the defendant's intention to develop a generic product, and (c) the plaintiffs' receipt of the defendant's notice concerning the ANDA — has sufficiently pleaded that the plaintiffs had knowledge of the defendant's expectation. (See dkt. 20 at

10–11, 24; dkt. 20-2 at 7; dkt. 20-7 at 2–5.) See Lightning Lube, 4 F.3d at 1167. Third, the defendant — in pointing out that the plaintiffs have brought this infringement action — has sufficiently pleaded that the plaintiffs have intentionally interfered with that expectation. See id. Fourth, the defendant — in alleging that it expected to receive FDA approval and to monetarily profit from the release of a generic — has sufficiently pleaded that there was a reasonable probability that it would have received the anticipated economic benefit in the absence of any interference by the plaintiffs. See id.¹ Fifth, the defendant's alleged damages due to lost profits based upon the plaintiffs' interference are apparent. See id.; Reckitt Benckiser Inc. v. Tris Pharma, No. 09-3125, 2011 WL 773034, at *7 (D.N.J. Feb. 28, 2011) (stating a tortious interference claim need only allege that the claimant "was in pursuit of business"). Thus, the Court will deny the part of the motion seeking to dismiss the Tortious Interference Counterclaim.

THE COURT stresses that the denial of the part of the motion seeking dismissal under Rule 12(b)(6) of the Counterclaims At Issue does not prevent the plaintiffs from moving for summary judgment in their favor later. "It is axiomatic that the standards for dismissing claims under Fed.R.Civ.P. 12(b)(6) and granting judgment under . . . Fed.R.Civ.P. 56 are vastly different". Fowler v. UPMC Shadyside, 578 F.3d 203, 213 (3d Cir. 2009). Indeed, a motion for summary judgment is reviewed under a more stringent

¹ Indeed, the plaintiffs do not argue that the defendant is facing any major regulatory issues before the FDA concerning the generic product. (See dkt. 19-1 at 19.)

standard than a motion to dismiss, and a well-pleaded claim may proceed even if the Court believes that actual proof of the facts alleged is improbable and that a recovery is unlikely. See id.; see also Watson v. Sec'y Pa. Dep't of Corr., 436 Fed.Appx. 131, 135 (3d Cir. 2011) (comparing analysis for summary judgment under Rule 56 with analysis for dismissal of claim under Rule 12(b)(6)).

BECAUSE THE COURT has stated the intention to deny the part of the motion insofar as it concerns the dismissal of the Counterclaims At Issue, a determination whether to bifurcate and stay discovery as to the Counterclaims At Issue is best left for the Magistrate Judge. Indeed, in the case relied upon by the plaintiffs here — Daiichi Pharm. Co. v. Apotex, Inc., 441 F.Supp.2d 672 (D.N.J. 2006) — the Magistrate Judge made that determination. See id. at 674 (stating magistrate judge severed counterclaim and stayed proceedings regarding severed counterclaim). (See dkt. 19-1 at 27–28.)²
Thus, the Court will deny the part of the motion concerning bifurcation and a stay, but

The plaintiff cited two other cases in support of the part of the motion concerning bifurcation and a stay. See Otsuka Pharm. Co. v. Torrent Pharm. Ltd., 118 F.Supp.3d 646 (D.N.J. 2015); Abraxis Bioscience v. Navinta LLC, No. 07-1251, 2008 WL 2967034 (D.N.J. July 31, 2008). (See dkt. 19-1 at 27.) Those cases are inapposite, because — unlike the current situation — the requests for bifurcation and a stay therein were unopposed. See Otsuka Pharm. Co., 118 F.Supp.3d at 659 (stating "parties uniformly assert that the Court should bifurcate and stay the Counterclaim pending resolution of the patent infringement issues", and granting bifurcation and a stay "[c]onsidering . . . the parties' agreement"); Abraxis Bioscience, 2008 WL 2967034, at *8 (stating defendant "does not oppose [plaintiff's] motion to bifurcate and to stay" the counterclaims).

will do so without prejudice to the plaintiffs to move again before the Magistrate Judge, if appropriate at this juncture.

THE COURT will issue an appropriate order.

s/ Mary L. Cooper

MARY L. COOPER

United States District Judge

Dated: May 27, 2016